March 26, 2020

Konan Medical, Inc.
% Alan Donald
President
Matrix Medical Consulting Inc
8880 Rio San Diego Drive Suite 800
San Diego, California 92108

Re: K191558
Trade/Device Name: Konan Specular Microscope XVII
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: February 12, 2020
Received: February 18, 2020

Dear Alan Donald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Ng
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191558

Device Name
Konan Specular Microscope XVII

Indications for Use *(Describe)*
The Konan Specular Microscope XVII, CellChek 20, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The following 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

510(k) Summary

Submitter Information

A.	Company Name:	Konan Medical, Inc.
B.	Company Address:	10-29, Miyanishicho, Nishinomiya Hyogo 662-0976, Japan
C.	Company Phone:	+81-798-36-3456
D.	Company facsimile:	+81-798-26-1028
E.	Contact Person:	Tatsuya Kasahara
F.	Date Summary Prepared:	March 23, 2020

Device Identification

A.	Device Trade Name:	Konan Specular Microscope XVII, CellChek 20
B.	Common Name:	Specular Microscope
C.	Classification Name(s):	AC-powered Slit Lamp Biomicroscope
D.	Classification Regulation(s):	886.1850
E.	Device Class:	Class 2
F.	Product Codes:	NQE
G.	Advisory Panel:	Ophthalmic

Identification of Predicate Device

The predicate device is the Konan Specular Microscope XIV, CellChek Plus, which was cleared by FDA under 510(k) number K120264 on April 11, 2012. In addition, the company has utilized the NONCON ROBO PACHY F&A, K062763, as a reference device.

Device Description

The Konan Specular Microscope XVII, CellChek 20, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of corneal endothelium and for measurement of the thickness of the cornea. Cell counting and analysis program are included, and allow for analysis of the images of the cell distribution of the eye.

When photographing the corneal endothelium, the device performs the alignment and automatically focuses by capturing the reflected light from patient's eye with the camera. The device permits visual inspection and photography of the corneal endothelium and measurement of the corneal thickness without any object contacting the eye. It features focusing by means of infrared techniques, as well as computer-assisted cell counting and cell analysis capabilities. The computer functions are also used to aid in setting up the various features of the machine and to aid in photography. Photographic images are temporarily stored in the system's memory and can be preserved by using a printer.

Both the image of the corneal endothelium and the various computerized control functions are displayed on the touch screen monitor.

The parts of the device that come into contact with a patient are the forehead rest and the chin rest. Their material is acrylonitrile butadiene styrene (ABS), the same material used in reference device and one with proven biocompatibility.

The function of the software installed in the device is to calculate mainly the cell density, the coefficient of variation of cell area and the percent hexagonality. In the manual methods, Actual identification if the cells and cell boundaries is done by the (physician) user. In the automatic method, the software detects the cells and cell boundaries, however, the user is given the opportunity to make corrections. In use, the user interacts with the software by visually placing dots in the center of cells as or by tracing cell boundaries as they appear or on a screen or uses the automatic algorithm.

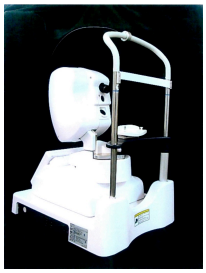
Indication for Use

The Konan Specular Microscope XVII, CellChek 20, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

Technological Characteristics

The Konan Specular Microscope XVII, CellChek 20, is technically equivalent to the Konan specular Microscope XIV, CellChek Plus. One of the principal design modifications for the device is that the mechanical unit used for alignment has changed. The mechanical unit of CellChek 20 has only three axes which work for X (right - left) - Y (up - down) - Z (forward - backward) alignment between the optics and a patient's eye. Therefore the patient needs to fixate on a peripheral target to obtain an image of endothelial cells at the peripheral position over the cornea. Another of the principal design modifications for the device is that the data analysis method has changed. The data analysis of CellChek 20 method consists of the Trace method with/without Auto-trace (which does not need to input parameter S, M, L or XL for analysis), the Center method with/without Auto-input (which uses the same algorithm as Auto-trace) and the Flex Center method with/without Auto-input (which uses the same algorithm as Auto-trace). A smaller CPU board (mother board) was implemented, and a new computer program was installed for the mechanical system and the data analysis system of CellChek 20.

Comparative table between CellChek Plus and CellChek 20			
Model name	**CellChek Plus**	**CellChek 20**	**Comparison**
510(k) No.	K120264	To Be Assigned by FDA	
Device name registered	Konan Specular Microscope XIV	Konan Specular Microscope XVII	
Intended use	The device is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the	The device is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of	Same

	cornea.	the cornea.	
Composition	The device is composed of the optical unit, the mechanical unit, the electrical unit and the display.	The device is composed of the optical unit, the mechanical unit and the power unit which includes the electrical unit and the display.	Different on expression. No safety/effectiveness concern.
Appearance			Different. No safety/effectiveness concern.
Size	683(H) x 365(W) x 451(D) mm	451(H) x 310(W) x 459(D) mm	Different. No safety/effectiveness concern.
Electric rating	Voltage: 100-230VAC Frequency: 50/60Hz, Power: 150VA	Voltage: 100-240VAC Frequency: 50/60Hz Power: 100VA	Almost same No safety/effectiveness concern.
Class (Electrical Safety)	Class I Type B applied part	Class I Type B applied part	Same
Operating Principle	The photographing the corneal endothelium, the device performs the alignment and automatically focuses by capturing the reflected light from the patient's eye with the camera.	The photographing the corneal endothelium, the device performs the alignment and automatically focuses by capturing the reflected light from the patient's eye with the camera.	Different on axes. No safety/effectiveness concern.

	The alignment is performed by 5 axes which are X (back and forth), Y (right and left), Z (up and down) θX (horizontal turn) and θY (vertical turn).	The alignment is performed by 3 axes which are X (back and forth), Y (right and left) and Z (up and down).	
Photographed Area	0.24 x 0.46 mm^2	0.25 x 0.55 mm^2	Almost same. No safety/effectiveness concern.
Analysis method	CellChek software: Corner method Auto trace method Center method ---------- Flex Center method ----------	CellChek software: Trace method Auto Trace method Center method Auto Center method F Center method Auto F Center method	Different (Algorithm of Trace method, Center method and F center method has not changed). No safety/effectiveness concern. ・ Nomenclature was changed "Corner method" to "Trace method" and "Flex Center method" to "F Center method". ・ The Auto trace method does not need to input parameter S, M, L or XL for analysis. ・ "Auto Center method" and "Auto F Center method" were added. They use the same

			algorithm of "Auto Trace method" and the center point of the endothelial cell is calculated as the gravity point of the endothelial cell by "Auto Trace method".
Materials of Patient Contacting Parts	PTFE (forehead rest) and ABS resin (chin rest)	ABS resin (forehead rest and chin rest)	Different. No safety/effectiveness concern. · Material of forehead rest was changed to the same material of chin rest.

Summary of Testing

A. Non Clinical Testings
The following testing was performed on the Konan Specular Microscope XVII, CellChek 20:

- The CellChek 20 device was subjected to electrical safety testing in accordance with ANSI/AAMI ES 60601-1.
- The CellChek 20 device was subjected to electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1-2.
- The CellChek 20 device was subjected to performance testing in accordance with ISO 15004-1.
- The CellChek 20 device was subjected to optical radiation safety testing in accordance with ANSI Z80.36.
- The CellChek 20 device was subjected to software validation testing in accordance with IEC 62304.

Performance Testing - Clinical

A prospective clinical study was conducted to assess the agreement, accuracy, and precision of the Konan Specular Microscope XVII, CellChek 20 by comparing the analytical results obtained with the NONCON ROBO PACHY F&A, a reference device, and also the predicate device for the Konan Specular Microscope XIV, CellChek Plus. This clinical performance testing includes the assessment of the agreement, accuracy, and precision of each of the 6 analysis methods, Trace Method, Auto Trace Method, Center Method, Auto Center Method, Flex Center Method, and Auto Flex Center Method of Konan Specular Microscope XVII, CellChek 20 by comparing with Center Method of NONCON ROBO PACHY F&A.

The examinees are all of the patients who came to the ophthalmic clinic, which has agreed to cooperate with this study, after the study start date. Some of the ophthalmic staffs basically photographed the right eyes of the examinees with Konan Specular Microscope XVII, CellChek 20 and NONCON ROBO PACHY F&A. However, when their right eyes could not be clearly photographed, the left eyes were photographed. Three analysts analyzed the examinees' images with each of the 6 methods, Center Method, Auto Center Method, Trace Method, Auto Trace Method, Flex Center Method, Auto Flex Center Method, of CellChek 20, and Center Method of F&A.
This study protocol pre-described criteria for the agreement limits is that the analysis result of each of the methods of CellChek 20 has a positive correlation with that of Center Method of F&A.

The mean (SD) age of the 80 subjects, whose breakdown was 55 females and 25 males, of this study was 65.6 (10.8) years.
No adverse events occurred in any examinees during this study. Additionally, no other safety issues of any kinds arose from the subject device and the reference device. The instruments of both of the devices were found to be safe and reliable in the assessment of corneal function.

The primary efficiency endpoints are the agreement and precision of the results for the 3 variables, that is, Corneal Endothelial Cell Density, Coefficient of Variation, and Hexagonality (hereinafter mentioned as CD, CV, and HEX, respectively). The discussion on the results of this performance testing is shown as follows.

I. Agreement/Accuracy Analysis (Comparison between subject device and reference device)

1) Cornea Measuring Area: Center Area

Analysis Method: Center Method of Subject Device and Reference Device

Table 1 Three Corneal Specular Microscopic Variables Assessed with Center Method of Subject Device and Reference Device – Center area

N=80	CD (/mm^2)	CV (%)	HEX (%)
NONCON ROBO PACHY F&A (Reference Device)			
Average (SD)	2717.1 (486.74)	33.8 (5.12)	58.1 (7.42)
Median	2738.5	33.0	58.3
Min – Max	849 - 3937	25 - 56	37 - 77
Konan Specular Microscope XVII, CellChek 20 (Subject Device)			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Device Comparisons			
Average Difference (SD)	215.6 (151.15)	0.3 (3.85)	1.8 (7.27)
Average Difference (SD) as a % of F&A reading	7.94% (5.563%)	0.74% (11.403%)	3.08% (12.523%)
95% LOA	(-86.7, 517.9)	(-7.5, 8.0)	(-12.8, 16.3)
Correlation (R^2)	0.9193	0.5677	0.2460
Deming Regression Intercept (95% CI)	107.6 (105.8, 109.4)	5.5 (3.6, 7.5)	32.5 (30.6, 34.5)
Deming Regression Slope (95% CI)	1.0 (1.0, 1.0)	0.8 (0.8, 0.9)	0.5 (0.4, 0.5)

Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation

The average differences were calculated as (Konan Specular Microscope XVII, CellChek 20) - (NONCON ROBO PACHY F&A).

The average differences as a % of NONCON ROBO PACHY F&A reading were calculated by dividing the average differences with the averages of the reference device.

The 95% LOA's were calculated as the average differences +/- 2SD's.

a) CD

Corneal endothelial cell density as measured with the subject device had the average (SD) of 2932.7 (527.83) compared with those of 2717.1 (486.74) for the reference device. The average difference (SD) were 215.6 (151.15).

The Deming regression lines had the associated R^2 value of 0.9193.

b) CV

Coefficient of Variation as measured with the subject device had the average (SD) of 34.0 (5.73) compared with those of 33.8 (5.12) for the reference device. The average difference (SD) were 0.3 (3.85).

The Deming regression lines had the associated R^2 value of 0.5677.

c) HEX

Percent of Hexagonality as measured with the subject device had the average (SD) of 59.9 (7.05) compared with those of 58.1 (7.42) for the reference device. The average difference (SD) were 1.8 (7.27).

The Deming regression lines had the associated R^2 value of 0.2460.

2) Cornea Measuring Area: Peripheral Area

Analysis Method: Center Method of Subject Device and Reference Device

Table 2 Three Corneal Specular Microscopic Variables Assessed with Center Method of Subject Device and Reference Device – Peripheral Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
NONCON ROBO PACHY F&A (Reference Device)			
Average (SD)	2782.4 (464.10)	33.5 (5.25)	58.8 (6.98)
Median	2825.0	32.9	59.0
Min – Max	884 - 3802	23 - 55	34 - 76
Konan Specular Microscope XVII, CellChek 20 (Subject Device)			
Average (SD)	2969.5 (507.65)	34.4 (6.36)	59.8 (6.00)
Median	3007.5	33.7	59.9
Min – Max	904 - 4021	25 - 61	42 - 71
Device Comparisons			
Average Difference (SD)	187.1 (144.61)	0.8 (4.57)	1.0 (7.28)
Average Difference (SD) as a % of F&A reading	6.72% (5.197%)	2.46% (13.642%)	1.67% (12.375%)

95% LOA	(-102.1, 476.3)	(-8.3, 10.0)	(-13.6, 15.5)
Correlation (R^2)	0.9209	0.4974	0.1439
Deming Regression Intercept (95% CI)	48.8 (46.9, 50.8)	5.7 (3.8, 7.6)	40.6 (38.6, 42.6)
Deming Regression Slope (95% CI)	1.0 (1.0, 1.1)	0.9 (0.8, 0.9)	0.3 (0.3, 0.4)

Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation

The average differences were calculated as (Konan Specular Microscope XVII, CellChek 20) - (NONCON ROBO PACHY F&A).

The average differences as a % of NONCON ROBO PACHY F&A reading were calculated by dividing the average differences with the averages of the reference device.

The 95% LOA's were calculated as the average differences +/- 2SD's.

a) CD

Corneal endothelial cell density as measured with the subject device had the average (SD) of 2969.5 (507.65) compared with those of 2782.4 (464.10) for the reference device. The average difference (SD) were 187.1 (144.61).

The Deming regression lines had the associated R^2 value of 0.9209.

b) CV

Coefficient of Variation as measured with the subject device had the average (SD) of 34.4 (6.36) compared with those of 33.5 (5.25) for the reference device. The average difference (SD) were 0.8 (4.57).

The Deming regression lines had the associated R^2 value of 0.4974.

c) HEX

Percent of Hexagonality as measured with the subject device had the average (SD) of 59.8 (6.00) compared with those of 58.8 (6.98) for the reference device. The average difference (SD) were 1.0 (7.28).

The Deming regression lines had the associated R^2 value of 0.1439.

II. Agreement/Accuracy Analysis (Comparison between Center Method vs Trace Method, Auto Trance Method, Auto Center Method, Flex Center Method, and Auto Flex Center Method of Subject Device (Konan Specular Microscope XVII, CellChek 20))

a) Corneal Measuring Area: Center Area

Analysis Method: Center Method vs Trace Method of Subject Device

Table 3 Three Corneal Specular Microscopic Variables Assessed with Two Analysis Methods – Center Method vs Trace Method – Center Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
Center Method			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Trace Method			
Average (SD)	2931.7 (531.31)	29.5 (7.68)	57.4 (7.78)
Median	2897.5	28.5	58.4
Min – Max	820 - 4565	17 - 52	38 - 73
Method Comparisons			
Average Difference (SD)	-1.0 (28.00)	-4.5 (4.13)	-2.4 (3.39)
Average Difference (SD) as a % of Center Method reading	-0.03% (0.955%)	-13.34% (12.132%)	-4.06% (5.671%)
95% LOA	(-57.0, 55.0)	(-12.8, 3.7)	(-9.2, 4.4)
Correlation (R^2)	0.9973	0.7215	0.8097
Deming Regression Intercept (95% CI)	-16.3 (-18.1, -14.5)	-9.2 (-11.3, -7.2)	-2.0 (-4.7, 0.7)
Deming Regression Slope (95% CI)	1.0 (1.0, 1.0)	1.1 (1.1, 1.2)	1.0 (0.9, 1.0)

Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation

The average differences were calculated as (Trace Method) - (Center Method).

The average differences as a % of Center Method reading were calculated by dividing the average differences with the averages of Center Method.

The 95% LOA's were calculated as the average differences +/- 2SD's.

(i) CD

Corneal endothelial cell density as measured with Trace Method had the average (SD) of 2931.7 (531.31) compared with those of 2932.7 (527.83) for Center Method. The average difference (SD) were -1.0 (28.00).

The Deming regression lines had the associated R^2 value of 0.9973.

(ii) CV

Corneal endothelial cell density as measured with Trace Method had the average (SD) of 29.5 (7.68) compared with those of 34.0 (5.73) for Center Method. The average difference (SD) were -4.5 (4.13).

The Deming regression lines had the associated R^2 value of 0.7215.

(iii) HEX

Corneal endothelial cell density as measured with Trace Method had the average (SD) of 57.4 (7.78) compared with 59.9 (7.05) for those of Center Method. The average difference (SD) were -2.4 (3.39).

The Deming regression lines had the associated R^2 value of 0.8097.

b) Cornea Measuring Area: Center Area

Analysis Method: Center Method vs Auto Trance Method of Subject Device

Table 4 Three Corneal Specular Microscopic Variables Assessed with Two Analysis Methods – Center Method vs Auto Trance Method – Center Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
Center Method			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Auto Trace Method			
Average (SD)	2756.1 (430.05)	19.5 (4.34)	59.5 (6.51)
Median	2816.0	19.0	60.0
Min – Max	900 - 3475	11 - 35	38 - 73
Device Comparisons			
Average Difference (SD)	-176.6 (213.31)	-14.5 (3.77)	-0.3 (5.80)
Average Difference (SD) as a % of Center Method	-6.02% (7.273%)	-42.67% (11.065%)	-0.58% (9.695%)

reading			
95% LOA	(-603.3, 250.0)	(-22.1, -7.0)	(-12.0, 11.3)
Correlation (R^2)	0.8479	0.5682	0.4050
Deming Regression Intercept (95% CI)	555.8 (554.2, 557.4)	0.1 (-1.5, 1.6)	24.3 (22.1, 26.5)
Deming Regression Slope (95% CI)	0.8 (0.7, 0.8)	0.6 (0.5, 0.6)	0.6 (0.6, 0.6)
Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation The average differences were calculated as (Auto Trace Method) - (Center Method). The average differences as a % of Center Method reading were calculated by dividing the average differences with the averages of Center Method. The 95% LOA's were calculated as the average differences +/- 2SD's.			

(i) CD

Corneal endothelial cell density as measured with Auto Trace Method had the average (SD) of 2756.1 (430.05) compared with those of 2932.7 (527.83) for Center Method. The average difference (SD) were -176.6 (213.31).

The Deming regression lines had the associated R^2 value of 0.8479.

(ii) CV

Corneal endothelial cell density as measured with Auto Trace Method had the average (SD) of 19.5 (4.34) compared with those of 34.0 (5.73) for Center Method. The average difference (SD) were -14.5 (3.77).

The Deming regression lines had the associated R^2 value of 0.5682.

(iii) HEX

Corneal endothelial cell density as measured with Auto Trace Method had the average (SD) of 59.5 (6.51) compared with those of 59.9 (7.05) for Center Method. The average difference (SD) were -0.3 (5.80).

The Deming regression lines had the associated R^2 value of 0.4050.

c) Cornea Measuring Area: Center Area

Analysis Method: Center Method vs Auto Center Method of Subject Device

Table 5 Three Corneal Specular Microscopic Variables Assessed with Two Analysis Method – Center Method vs Auto Center Method – Center Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
Center Method			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Auto Center Method			
Average (SD)	2777.7 (433.55)	34.3 (5.83)	59.8 (6.96)
Median	2828.0	34.5	60.0
Min – Max	921 - 3434	24 - 55	36 - 71
Device Comparisons			
Average Difference (SD)	-155.0 (210.98)	0.3 (3.39)	-0.1 (4.67)
Average Difference (SD) as a % of Center Method reading	-5.29% (7.194%)	0.75% (9.966%)	-0.16% (7.796%)
95% LOA	(-577.0, 266.9)	(-6.5, 7.0)	(-9.4, 9.2)
Correlation (R^2)	0.8504	0.6854	0.6055
Deming Regression Intercept (95% CI)	556.3 (554.7, 557.9)	5.6 (3.9, 7.4)	13.8 (11.4, 16.2)
Deming Regression Slope (95% CI)	0.8 (0.8, 0.8)	0.8 (0.8, 0.9)	0.8 (0.7, 0.8)

Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation

The average differences were calculated as (Auto Center Method) - (Center Method).

The average differences as a % of Center Method reading were calculated by dividing the average differences with the averages of Center Method.

The 95% LOA's were calculated as the average differences +/- 2SD's.

(i) CD

Corneal endothelial cell density as measured with Auto Center Method had the average (SD) of 2777.7 (433.55) compared with those of 2932.7 (527.83) for Center Method. The average difference (SD) were -155.0 (210.98).

The Deming regression lines had the associated R^2 value of 0.8504.

(ii) CV

Corneal endothelial cell density as measured with Auto Center Method had the average (SD) of 34.3 (5.83) compared with those of 34.0 (5.73) for Center Method. The average difference (SD) were 0.3 (3.39).

The Deming regression lines had the associated R^2 value of 0.6854.

(iii) HEX

Corneal endothelial cell density as measured with Auto Center Method had the average (SD) of 59.8 (6.96) compared with those of 59.9 (7.05) for Center Method. The average difference (SD) were -0.1 (4.67).

The Deming regression lines had the associated R^2 value of 0.6055.

d) Cornea Measuring Area: Center Area

Analysis Method: Center Method vs Flex Center Method of Subject Device

Table 6 Three Corneal Specular Microscopic Variables Assessed with Two Analysis Method – Center Method vs Flex Center Method – Center Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
Center Method			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Flex Center Method			
Average (SD)	2917.8 (531.26)	36.0 (5.80)	59.9 (5.91)
Median	2899.2	35.0	60.2
Min – Max	822 - 4524	26 - 57	48 - 74
Device Comparisons			
Average Difference (SD)	-14.9 (28.88)	2.0 (1.74)	0.1 (3.47)
Average Difference (SD) as a % of Center Method	-0.51% (0.985%)	5.85% (5.106%)	0.09% (5.798%)

reading			
95% LOA	(-72.6, 42.9)	(-1.5, 5.5)	(-6.9, 7.0)
Correlation (R^2)	0.9971	0.9114	0.7587
Deming Regression Intercept (95% CI)	-29.6 (-31.4, -27.8)	3.1 (1.3, 5.0)	16.2 (13.9, 18.6)
Deming Regression Slope (95% CI)	1.0 (1.0, 1.0)	1.0 (0.9, 1.0)	0.7 (0.7, 0.8)
Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation The average differences were calculated as (Flex Center Method) - (Center Method). The average differences as a % of Center Method reading were calculated by dividing the average differences with the averages of Center Method. The 95% LOA's were calculated as the average differences +/- 2SD's.			

(i) CD

Corneal endothelial cell density as measured with Flex Center Method had the average (SD) of 2917.8 (531.26) compared with those of 2932.7 (527.83) for Center Method. The average difference (SD) were -14.9 (28.88).

The Deming regression lines had the associated R^2 value of 0.9971.

(ii) CV

Corneal endothelial cell density as measured with Flex Center Method had the average (SD) of 36.0 (5.80) compared with those of those of 34.0 (5.73) for Center Method. The average difference (SD) were 2.0 (1.74).

The Deming regression lines had the associated R^2 value of 0.9114.

(iii) HEX

Corneal endothelial cell density as measured with Flex Center Method had the average (SD) of 59.9 (5.91) compared with those of 59.9 (7.05) for Center Method. The average difference (SD) were 0.1 (3.47).

The Deming regression lines had the associated R^2 value of 0.7587.

e) Cornea Measuring Area: Center Area

Analysis Method: Center Method vs Auto Flex Center Method of Subject Device

Table 7 Three Corneal Specular Microscopic Variables Assessed with Two Analysis Method – Center Method vs Auto Flex Center Method – Center Area

N=80	CD (/mm^2)	CV (%)	HEX (%)
Center Method			
Average (SD)	2932.7 (527.83)	34.0 (5.73)	59.9 (7.05)
Median	2915.9	33.2	59.9
Min – Max	816 - 4532	25 - 52	40 - 74
Auto Flex Center Method			
Average (SD)	2760.8 (433.37)	35.1 (5.84)	59.6 (6.83)
Median	2835.0	35.0	60.0
Min – Max	905 - 3415	24 - 58	38 - 70
Device Comparisons			
Average Difference (SD)	-172.0 (212.44)	1.1 (3.60)	-0.3 (5.59)
Average Difference (SD) as a % of Center Method reading	-5.86% (7.244%)	3.21% (10.586%)	-0.47% (9.342%)
95% LOA	(-596.9, 252.9)	(-6.1, 8.3)	(-11.5, 10.9)
Correlation (R^2)	0.8480	0.6499	0.4564
Deming Regression Intercept (95% CI)	543.5 (541.9, 545.0)	7.2 (5.4, 8.9)	20.4 (18.1, 22.7)
Deming Regression Slope (95% CI)	0.8 (0.8, 0.8)	0.8 (0.8, 0.9)	0.7 (0.6, 0.7)

Abbreviations: CD = corneal endothelial cell density; CI = confidence interval; CV = coefficient of variation; HEX = hexagonality; LOA = limits of agreement; SD = standard deviation

The average differences were calculated as (Auto Flex Center Method) - (Center Method).

The average differences as a % of Center Method reading were calculated by dividing the average differences with the averages of Center Method.

The 95% LOA's were calculated as the average differences +/- 2SD's.

(i) CD

Corneal endothelial cell density as measured with Auto Flex Center had the average (SD) of 2760.8 (433.37) compared with those of 2932.7 (527.83) for Center Method. The average difference (SD) were -172.0 (212.44).

The Deming regression lines had the associated R^2 value of 0.8480.

(ii) CV

Corneal endothelial cell density as measured with Auto Flex Center had the average (SD) of 35.1 (5.84) compared with those of 34.0 (5.73) for Center Method. The average difference (SD) were 1.1 (3.60).

The Deming regression lines had the associated R^2 value of 0.6499.

(iii) HEX

Corneal endothelial cell density as measured with Auto Flex Center had the average (SD) of 59.6 (6.83) compared with those of 59.9 (7.05) for Center Method. The average difference (SD) were -0.3 (5.59).

The Deming regression lines had the associated R^2 value of 0.4564.

III. Precision Analysis

1) Cornea Measuring Area: Center Area

Analysis Method: Center Method of Subject Device vs Center Method of Reference Device

Table 8 Precision Analyses for Center Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Center Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	9.1	9.8
Repeatability SD as a% of the Average	0.3%	0.4%
Repeatability limit	25.5	27.4
Repeatability Ratio (CellChek 20/F&A)	0.9286	-----
Reproducibility SD	53.2	99.3
Reproducibility SD as a% of the Average	1.8%	3.8%
Reproducibility limit	149.0	278.0
Reproducibility Ratio (CellChek 20/F&A)	0.5358	-----
CV		
Repeatability SD	0.4	0.6

Repeatability SD as a% of the Average	1.2%	1.8%
Repeatability limit	1.1	1.7
Repeatability Ratio (CellChek 20/F&A)	0.6667	-----
Reproducibility SD	0.9	3.2
Reproducibility SD as a% of the Average	2.7%	9.1%
Reproducibility limit	2.5	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.2813	-----
HEX		
Repeatability SD	0.8	1.2
Repeatability SD as a% of the Average	1.3%	2.1%
Repeatability limit	2.2	3.4
Repeatability Ratio (CellChek 20/F&A)	0.6667	-----
Reproducibility SD	1.3	2.2
Reproducibility SD as a% of the Average	2.2%	3.8%
Reproducibility limit	3.6	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.5909	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

2) Cornea Measuring Area: Center Area

Analysis Method: Trace Method of Subject Device vs Center Method of Reference Device

Table 9 Precision Analyses for Trace Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Trace Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	12.1	9.8
Repeatability SD as a% of the Average	0.4%	0.4%
Repeatability limit	33.9	27.4
Repeatability Ratio (CellChek 20/F&A)	1.2347	-----
Reproducibility SD	38.6	99.3
Reproducibility SD as a% of the Average	1.3%	3.8%
Reproducibility limit	108.1	278.0
Reproducibility Ratio (CellChek 20/F&A)	0.3887	-----
CV		

Repeatability SD	0.9	0.6
Repeatability SD as a% of the Average	3.1%	1.8%
Repeatability limit	2.5	1.7
Repeatability Ratio (CellChek 20/F&A)	1.5000	-----
Reproducibility SD	2.8	3.2
Reproducibility SD as a% of the Average	8.9%	9.1%
Reproducibility limit	7.8	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.8750	-----
HEX		
Repeatability SD	0.6	1.2
Repeatability SD as a% of the Average	1.0%	2.1%
Repeatability limit	1.7	3.4
Repeatability Ratio (CellChek 20/F&A)	0.5000	-----
Reproducibility SD	1.7	2.2
Reproducibility SD as a% of the Average	3.0%	3.8%
Reproducibility limit	4.8	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.7727	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

3) Cornea Measuring Area: Center Area

Analysis Method: Auto Trace Method of Subject Device vs Center Method of Reference Device

Table 10 Precision Analyses for Auto Trace Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Auto Trace Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	0.0	9.8
Repeatability SD as a% of the Average	0.0%	0.4%
Repeatability limit	0.0	27.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	22.4	99.3
Reproducibility SD as a% of the Average	0.8%	3.8%
Reproducibility limit	62.7	278.0
Reproducibility Ratio (CellChek 20/F&A)	0.2256	-----

CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	0.7	3.2
Reproducibility SD as a% of the Average	3.6%	9.1%
Reproducibility limit	2.0	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.2188	-----
HEX		
Repeatability SD	0.0	1.2
Repeatability SD as a% of the Average	0.0%	2.1%
Repeatability limit	0.0	3.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.4	2.2
Reproducibility SD as a% of the Average	2.4%	3.8%
Reproducibility limit	3.9	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.6364	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

4) Cornea Measuring Area: Center Area

Analysis Method: Auto Center Method of Subject Device vs Center Method of Reference Device

Table 11 Precision Analyses for Auto Center Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Auto Center Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	0.0	9.8
Repeatability SD as a% of the Average	0.0%	0.4%
Repeatability limit	0.0	27.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	21.0	99.3
Reproducibility SD as a% of the Average	0.8%	3.8%
Reproducibility limit	58.8	278.0

Reproducibility Ratio (CellChek 20/F&A)	0.2115	-----
CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.0	3.2
Reproducibility SD as a% of the Average	2.9%	9.1%
Reproducibility limit	2.8	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.3125	-----
HEX		
Repeatability SD	0.0	1.2
Repeatability SD as a% of the Average	0.0%	2.1%
Repeatability limit	0.0	3.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.5	2.2
Reproducibility SD as a% of the Average	2.5%	3.8%
Reproducibility limit	4.2	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.6818	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

5) Cornea Measuring Area: Center Area

Analysis Method: Flex Center Method of Subject Device vs Center Method of Reference Device

Table 12 Precision Analyses for Flex Center Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Flex Center Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	12.2	9.8
Repeatability SD as a% of the Average	0.4%	0.4%
Repeatability limit	34.2	27.4
Repeatability Ratio (CellChek 20/F&A)	1.2449	-----
Reproducibility SD	34.3	99.3
Reproducibility SD as a% of the Average	1.2%	3.8%

Reproducibility limit	96.0	278.0
Reproducibility Ratio (CellChek 20/F&A)	0.3454	-----
CV		
Repeatability SD	1.0	0.6
Repeatability SD as a% of the Average	2.8%	1.8%
Repeatability limit	2.8	1.7
Repeatability Ratio (CellChek 20/F&A)	1.6667	-----
Reproducibility SD	1.3	3.2
Reproducibility SD as a% of the Average	3.6%	9.1%
Reproducibility limit	3.6	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.4063	-----
HEX		
Repeatability SD	1.4	1.2
Repeatability SD as a% of the Average	2.3%	2.1%
Repeatability limit	3.9	3.4
Repeatability Ratio (CellChek 20/F&A)	1.1667	-----
Reproducibility SD	1.8	2.2
Reproducibility SD as a% of the Average	3.0%	3.8%
Reproducibility limit	5.0	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.8182	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

6) Cornea Measuring Area: Center Area

Analysis Method: Auto Flex Center Method of Subject Device vs Center Method of Reference Device

Table 13 Precision Analyses for Auto Flex Center Method of Subject Device vs Center Method of Reference Device – Center Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Auto Flex Center Method	NONCON ROBO PACHY F&A (Reference Device) Center Method
CD		
Repeatability SD	0.0	9.8
Repeatability SD as a% of the Average	0.0%	0.4%
Repeatability limit	0.0	27.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----

Reproducibility SD	22.6	99.3
Reproducibility SD as a% of the Average	0.8%	3.8%
Reproducibility limit	63.3	278.0
Reproducibility Ratio (CellChek 20/F&A)	0.2276	-----
CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	0.9	3.2
Reproducibility SD as a% of the Average	2.6%	9.1%
Reproducibility limit	2.5	9.0
Reproducibility Ratio (CellChek 20/F&A)	0.2813	-----
HEX		
Repeatability SD	0.0	1.2
Repeatability SD as a% of the Average	0.0%	2.1%
Repeatability limit	0.0	3.4
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.4	2.2
Reproducibility SD as a% of the Average	2.4%	3.8%
Reproducibility limit	3.9	6.2
Reproducibility Ratio (CellChek 20/F&A)	0.6364	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

7) Cornea Measuring Area: Peripheral Area

Analysis Method: Center Method of Subject Device vs Center Method of Reference Device

Table 14 Precision Analyses for Center Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Center Method N=80	NONCON ROBO PACHY F&A (Reference Device) Center Method N=80
CD		
Repeatability SD	9.7	9.7
Repeatability SD as a% of the Average	0.3%	0.3%

Repeatability limit	27.2	27.2
Repeatability Ratio (CellChek 20/F&A)	1.0000	-----
Reproducibility SD	54.0	113.4
Reproducibility SD as a% of the Average	1.8%	4.2%
Reproducibility limit	151.2	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.4762	-----
CV		
Repeatability SD	0.9	0.6
Repeatability SD as a% of the Average	2.6%	1.8%
Repeatability limit	2.5	1.7
Repeatability Ratio (CellChek 20/F&A)	1.5000	-----
Reproducibility SD	1.9	3.9
Reproducibility SD as a% of the Average	5.5%	11.0%
Reproducibility limit	5.3	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.4872	-----
HEX		
Repeatability SD	1.3	1.3
Repeatability SD as a% of the Average	2.2%	2.2%
Repeatability limit	3.6	3.6
Repeatability Ratio (CellChek 20/F&A)	1.0000	-----
Reproducibility SD	1.7	2.5
Reproducibility SD as a% of the Average	2.9%	4.3%
Reproducibility limit	4.8	7.0
Reproducibility Ratio (CellChek 20/F&A)	0.6800	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

8) Cornea Measuring Area: Peripheral Area

Analysis Method: Trace Method of Subject Device vs Center Method of Reference Device

Table 15 Precision Analyses for Trace Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Trace Method N=80	NONCON ROBO PACHY F&A (Reference Device) Center Method N=80
CD		

Repeatability SD	10.8	9.7
Repeatability SD as a% of the Average	0.4%	0.3%
Repeatability limit	30.2	27.2
Repeatability Ratio (CellChek 20/F&A)	1.1134	-----
Reproducibility SD	43.9	113.4
Reproducibility SD as a% of the Average	1.5%	4.2%
Reproducibility limit	122.9	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.3871	-----
CV		
Repeatability SD	0.9	0.6
Repeatability SD as a% of the Average	3.0%	1.8%
Repeatability limit	2.5	1.7
Repeatability Ratio (CellChek 20/F&A)	1.5000	-----
Reproducibility SD	3.0	3.9
Reproducibility SD as a% of the Average	9.3%	11.0%
Reproducibility limit	8.4	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.7692	-----
HEX		
Repeatability SD	0.6	1.3
Repeatability SD as a% of the Average	1.0%	2.2%
Repeatability limit	1.7	3.6
Repeatability Ratio (CellChek 20/F&A)	0.4615	-----
Reproducibility SD	1.8	2.5
Reproducibility SD as a% of the Average	3.2%	4.3%
Reproducibility limit	5.0	7.0
Reproducibility Ratio (CellChek 20/F&A)	0.7200	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

9) Cornea Measuring Area: Peripheral Area

Analysis Method: Auto Trace Method of Subject Device vs Center Method of Reference Device

Table 16 Precision Analyses for Auto Trace Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Auto Trace Method	NONCON ROBO PACHY F&A (Reference Device) Center Method N=80

	N=80	
CD		
Repeatability SD	0.0	9.7
Repeatability SD as a% of the Average	0.0%	0.3%
Repeatability limit	0.0	27.2
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	31.0	113.4
Reproducibility SD as a% of the Average	1.1%	4.2%
Reproducibility limit	86.8	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.2734	-----
CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.1	3.9
Reproducibility SD as a% of the Average	5.4%	11.0%
Reproducibility limit	3.1	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.2821	-----
HEX		
Repeatability SD	0.0	1.3
Repeatability SD as a% of the Average	0.0%	2.2%
Repeatability limit	0.0	3.6
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	3.2	2.5
Reproducibility SD as a% of the Average	5.5%	4.3%
Reproducibility limit	9.0	7.0
Reproducibility Ratio (CellChek 20/F&A)	1.2800	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

10) Cornea Measuring Area: Peripheral Area

Analysis Method: Auto Center Method of Subject Device vs Center Method of Reference Device

Table 17 Precision Analyses for Auto Center Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular Microscope XVII, CellChek 20	NONCON ROBO PACHY F&A (Reference Device)

	(Subject Device) Auto Center Method N=80	Center Method N=80
CD		
Repeatability SD	0.0	9.7
Repeatability SD as a% of the Average	0.0%	0.3%
Repeatability limit	0.0	27.2
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	27.7	113.4
Reproducibility SD as a% of the Average	1.0%	4.2%
Reproducibility limit	77.6	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.2443	-----
CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.1	3.9
Reproducibility SD as a% of the Average	3.2%	11.0%
Reproducibility limit	3.1	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.2821	-----
HEX		
Repeatability SD	0.0	1.3
Repeatability SD as a% of the Average	0.0%	2.2%
Repeatability limit	0.0	3.6
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.5	2.5
Reproducibility SD as a% of the Average	2.5%	4.3%
Reproducibility limit	4.2	7.0
Reproducibility Ratio (CellChek 20/F&A)	0.6000	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

11) Cornea Measuring Area: Peripheral Area

Analysis Method: Flex Center Method of Subject Device vs Center Method of Reference Device

Table 18 Precision Analyses for Flex Center Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular	NONCON ROBO

510(k) Summary – Konan Specular Microscope XVII, CellChek 20

	Microscope XVII, CellChek 20 (Subject Device) Flex Center Method N=80	PACHY F&A (Reference Device) Center Method N=80
CD		
Repeatability SD	13.2	9.7
Repeatability SD as a% of the Average	0.4%	0.3%
Repeatability limit	37.0	27.2
Repeatability Ratio (CellChek 20/F&A)	1.3608	-----
Reproducibility SD	57.7	113.4
Reproducibility SD as a% of the Average	2.0%	4.2%
Reproducibility limit	161.6	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.5088	-----
CV		
Repeatability SD	0.9	0.6
Repeatability SD as a% of the Average	2.5%	1.8%
Repeatability limit	2.5	1.7
Repeatability Ratio (CellChek 20/F&A)	1.5000	-----
Reproducibility SD	1.2	3.9
Reproducibility SD as a% of the Average	3.4%	11.0%
Reproducibility limit	3.4	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.3077	-----
HEX		
Repeatability SD	1.3	1.3
Repeatability SD as a% of the Average	2.2%	2.2%
Repeatability limit	3.6	3.6
Repeatability Ratio (CellChek 20/F&A)	1.0000	-----
Reproducibility SD	1.4	2.5
Reproducibility SD as a% of the Average	2.4%	4.3%
Reproducibility limit	3.9	7.0
Reproducibility Ratio (CellChek 20/F&A)	0.5600	-----
N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images). The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component. The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.		

12) Cornea Measuring Area: Peripheral Area

Analysis Method: Auto Flex Center Method of Subject Device vs Center Method of Reference Device

Table 19 Precision Analyses for Auto Flex Center Method of Subject Device vs Center Method of Reference Device – Peripheral Area

Variable	Konan Specular Microscope XVII, CellChek 20 (Subject Device) Auto Flex Center Method N=80	NONCON ROBO PACHY F&A (Reference Device) Center Method N=80
CD		
Repeatability SD	0.0	9.7
Repeatability SD as a% of the Average	0.0%	0.3%
Repeatability limit	0.0	27.2
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	28.1	113.4
Reproducibility SD as a% of the Average	1.0%	4.2%
Reproducibility limit	78.7	317.5
Reproducibility Ratio (CellChek 20/F&A)	0.2478	-----
CV		
Repeatability SD	0.0	0.6
Repeatability SD as a% of the Average	0.0%	1.8%
Repeatability limit	0.0	1.7
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.2	3.9
Reproducibility SD as a% of the Average	3.4%	11.0%
Reproducibility limit	3.4	10.9
Reproducibility Ratio (CellChek 20/F&A)	0.3077	-----
HEX		
Repeatability SD	0.0	1.3
Repeatability SD as a% of the Average	0.0%	2.2%
Repeatability limit	0.0	3.6
Repeatability Ratio (CellChek 20/F&A)	0.0000	-----
Reproducibility SD	1.4	2.5
Reproducibility SD as a% of the Average	2.4%	4.3%
Reproducibility limit	3.9	7.0
Reproducibility Ratio (CellChek 20/F&A)	0.5600	-----

N represents the total number of subjects in each eye population in the precision and agreement cohort with complete data (80 total images).
The repeatability limit was 2.8 times the repeatability standard deviation, which is the square root of the residual within subject variance component.
The reproducibility limit is 2.8 times the reproducibility standard deviation, which is the square root of the sum of the variance components of operator + device, operator + device x subject interaction, and residual within subject.

Conclusion

I. Agreement/Accuracy Analysis

As shown in Table 14, regardless of the difference of the corneal measuring areas, that is, center area and peripheral area, all of the variables, CD, CV, and HEX, measured by Center Method of Konan Specular Microscope XVII, CellChek 20 showed very high correlations with those by Center Method of NONCON ROBO PACHY F&A.

As shown in Table 15, as for Konan Specular Microscope XVII, CellChek 20, all of the variables measured by Trace Method, Auto Trace Method, Auto Center Method, Flex Center Method, and Auto Flex Center Method showed very high correlations with those by Center Method, respectively.

II. Precision Analysis

As for all of the measured variables, CD, CV, and HEX, the repeatability and reproducibility measured by Center Method of Konan Specular Microscope XVII, CellChek 20 were superior to those measured by Center Method of NONCON ROBO PACHY F&A.

As for Auto Trace Method, Auto Center Method, and Auto Flex Center Method of Konan Specular Microscope XVII, CellChek 20, their repeatability and reproducibility of all of the variables were very superior to those by Center Method of NONCON ROBO PACHY F&A.

Additionally, the repeatability and reproducibility of Trace Method and Flex Center Meth of Konan Specular Microscope XVII, CellChek 20 were partially superior to or equivalent with those by Center Method of NONCON ROBO PACHY F&A.

From the above, the agreement, accuracy, and precision of the Konan Specular Microscope XVII, CellChek 20 demonstrates that it is substantially equivalent to the NONCON ROBO PACHY F&A. Please note that in the above studies we compared agreement, accuracy, and precision between the subject device and the reference device NONCON ROBO PACHY F&A cleared under K062763. However, in K120264 submission we demonstrated substantial equivalence between Konan Specular Microscope XIV, CellChek Plus (predicate to the subject device) and NONCON ROBO PACHY F&A (reference device). Therefore, based on the current results and K120264 studies we conclude substantial equivalence in the clinical performance of the subject device to the predicate.

Table 14 Agreement between Konan Specular Microscope XVII, CellChek 20 and NONCON ROBO PACHY F&A

Measuring Position	Variables	Correlation
Center	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Strong Positive Correlation
Peripheral	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Week Positive Correlation

Table 15 Agreement between Center Method and Other Methods of Konan Specular Microscope XVII, CellChek 20

Analysis Method	Variables	Correlation
Trace	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Strong Positive Correlation
Auto Trace	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Positive Correlation
Auto Center	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Strong Positive Correlation
Flex Center	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Strong Positive Correlation
Auto Flex Center	CD	Strong Positive Correlation
	CV	Strong Positive Correlation
	HEX	Positive Correlation

Conclusions Drawn from Studies

The conclusion drawn from the non-clinical and the clinical testing data demonstrates that the Konan Specular Microscope XVII, CellChek 20, is substantially equivalent to the predicate device, the Konan Specular Microscope XIV, CellChek Plus.